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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/684,759

10/14/2003

Li Wang

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EXAMINER

ALTER, ALYSSA M

ART UNIT

PAPER NUMBER

3762

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/684,759	<b>Applicant(s)</b> WANG ET AL.	
	<b>Examiner</b> ALYSSA M. ALTER	<b>Art Unit</b> 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-13, 15-36, 38-55, 57-62 and 65-71 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13, 15-36, 38-55, 57-62 and 65-71 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Allowable Subject Matter***

The indicated allowability of claims 1-13, 15-36, 38-46, 49-62 and 65-71 is withdrawn in view of the newly discovered reference(s) to Combs et al. (US 6512949 B1). Rejections based on the newly cited reference(s) follow.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1-13, 15-36, 38-55, 57-62 and 65-71 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no support in the specification for the terms “wetter” or “drier” condition. Furthermore, the limitation of “once per day on different days” is also not found in the specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 27-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

applicant regards as the invention. The claims recite the limitation "the pulse of energy". There is insufficient antecedent basis for this limitation in the claims.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1-2, 8-11, 13, 15-18, 24-25, 27-34, 36, 38-41, 47-55, 57-60 and 70-71 are rejected under 35 U.S.C. 102(e) as being anticipated by Combs et al. (US 6,512,949 B1). Combs et al. discloses a system, as seen in figure 1 and 7, to measure intra-thoracic impedance, removing noise from the signal by filtering and manipulating the data to determine an evaluation of edema, which the examiner considers to be an "indication" of a wetter or drier condition (i.e, worsening or improving edema).

As to claims 2, 25 and 50, "Another preferred way to remove heart and breath cycle noise is to synchronize to the measurement so as to measure only at the same point in the cycles. This is made possible in pacemakers that already use impedance measurements to detect Minute Ventilation (such as can be found in the Kappa 400) pacemakers by Medtronic, or the META DDDR by Telectronics/St. Jude Medical, since they keep track of the breathing cycle and the heart cycle already. By simply adding a

trigger signal generator to signal the measurement circuits at a particular value, and then storing the impedance at the time such signal is generated thereby designating it the DC impedance value, the required result is accomplished for that cycle. The trigger signal should preferably coincide with the nearest upcoming preprogrammed measurement time, preferably at 5-15 minute intervals, but anything up to each cycle or every hour would be reasonable”(col. 8, lines 7-22).

As to claims 9, 32 and 52, “Filtering can be implemented in this block as desired. Preferably band pass poles of 0.05 Hz to 0.5 Hz can be realized and we prefer a switched capacitor bandpass filter” (col. 7, lines 27-29). The examiner considers this filter to be a low pass filter.

As to claims 10-11, 13, 33-34, 36 and 53-55, figure 12 disclose the use of a coil electrode 124 and a button electrode 129 located on the canister or ICD housing.

As to claims 15-16, 39 and 58, “In the clinical setting the doctor will use a programmer device which is either a hand held unit like the PH unit which is held in proximity to the body B or a hand held device associated with a larger "programmer" which in common use is similar in power to a personal computer running an Intel 80486 or Pentium processor” (col. 13, lines 4-9). Therefore, since the system can employ a computer, there would necessarily be a colored display.

As to claims 17, 40 and 59, “Protection circuits are often provided in implanted devices such as circuits 31A and B in order to protect the more sensitive electronics of the device from electrosurgical cautery in, or defibrillation of, the patient.”(col. 6, L 9-12).

As to claims 18, 41 and 60, "modification of ICD therapies to trigger a defibrillation pulse without resorting to precursor therapies prior to defibrillation in the presence of high levels of edema may be suitable, since in the presence of edema the heart is less likely to be responsive to precursor electrical pulse therapies" (col. 18, lines 62-67).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 3-7, 12, 19-23, 26, 35, 42-46, 61-62 and 65-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Combs et al. (US 6,512,949 B1). Combs et al. discloses the claimed invention except for the performance of a cross-check for impedance values. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the collection of impedance data to include a means for cross-checking impedance data since such a modification would provide the predictable results of ensuring the accuracy of the data collected.

As to claims 3-7 and 26, Combs et al. discloses the claimed invention except for the range of the interval after deliver of a pacing pulse. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified

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the interval after the pacing pulse to be within 10 to 30 milliseconds in order to provide the predictable results of modifying the treatment to meet specific patient needs.

Furthermore, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233 (see MPEP 2144.05).

As to claims 12, 35 and 65-66, Combs et al. discloses the claimed invention except for the location of the first electrode being disposed in the superior vena cava or in the coronary sinus. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the location of the electrodes in order to provide the predictable result of modifying the system to meet specific patient needs.

Furthermore, it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70 (see MPEP 2144.04).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALYSSA M. ALTER whose telephone number is (571)272-4939. The examiner can normally be reached on M-F 9am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/  
Primary Examiner, Art Unit 3762

/Alyssa M Alter/  
Examiner  
Art Unit 3762